



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,354	06/27/2003	Stanley T. Crook	MSIBIS-0002USC2	2899
27180 7590 10/05/2009 ISIS PHARMACEUTICALS INC 1896 RUTHERFORD RD. CARLSBAD, CA 92008				
EXAMINER				
LU, FRANK WEI MIN				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
10/05/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/608,354

Applicant(s)

CROOK ET AL.

Examiner

FRANK W. LU

Art Unit

1634

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38, 39, 95, 97-99, 101, 103, 104 and 109-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38, 39, 95, 97-99, 101, 103, 104 and 109-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/3/2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on July 1, 2009 have been entered. The claims pending in this application are claims 38, 39, 95, 97-99, 101, 103, 104, and 109-114. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on July 1, 2009.

Specification

2. The amendment filed on July 1, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the disclosure of each of U.S. Patents 6,656,690, 6,329,146 and 6,428,956 is incorporated herein by reference in its entirety because this application was filed before September 21, 2004 and original filed specification only describes incorporation of case 09/076,206, which is U.S. Patent No. 6,428,956, by reference.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 38, 39, 95, 97-99, 101, 103, 104, and 109-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 111 is rejected as vague and indefinite. Since step (f) does not indicate which mass to charge ratio of step (e) means that one or more members of said mixture of compounds binds to the nucleic acid target and which mass to charge ratio of step (e) means that one or more members of said mixture of compounds does not bind to the nucleic acid target, it is unclear how whether binding of one or more members of said mixture of compounds to the nucleic acid target has occurred can be determined by comparing at least one mass to charge ratio obtained in step (e) to the known mass to charge ratio of the complex. Please clarify.
6. Claim 111 is rejected as vague and indefinite. Since step (c) does not indicate which member in a mixture of known compound has a high mass and which member in a mixture of known compound has a low mass, it is unclear how the identity of said one or more members can be determined by calculating the mass of said one or more members as recited in step (g). Please clarify.
7. Claim 112 is rejected as vague and indefinite. Since step (g) does not indicate which mass to charge ratio of step (f) means that one or more members of said mixture of compounds binds to the nucleic acid target and which mass to charge ratio of step (f) means that one or more members of said mixture of compounds does not bind to the nucleic acid target, it is unclear how whether binding of one or more members of said mixture of compounds to the nucleic acid target

has occurred can be determined by comparing the mass to charge ratio collected in steps (c) and (f). Please clarify.

8. Claim 112 is rejected as vague and indefinite. Since step (d) does not indicate which member in a mixture of known compound has a high mass and which member in a mixture of known compound has a low mass, it is unclear how the identity of said one or more members can be determined by calculating the mass of said one or more members as recited in step (h). Please clarify.

9. Claim 113 or 114 is rejected as vague and indefinite. Since the claim does not mention the dissociation constant for the standard binding compound and said nucleic acid target, it is unclear how to calculate a relative dissociation constant for said member by comparing the ion abundance of said one or more members to the known ion abundance of the complex and thereby determining binding affinity of said member for said nucleic acid target. Furthermore, the phrase "a relative dissociation constant for said member" in the claim is incorrect, correct term should be a relative dissociation constant for said member and said nucleic acid target. Please clarify.

Response to Arguments

10. Applicant's arguments with respect to claims 38, 39, 95, 97-99, 101, 103, 104, and 109-114 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of

such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on (571)272-0763.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
September 30, 2009